Application Number: 10/546,139 Docket: 34076/US/2 Response to Office Action of August 8, 2007

### Remarks

#### **Examiner Interview Summary**

On January 30, 2008, Attorney Fairman conducted a telephonic interview with Examiner Long regarding the notice of non-compliant amendment mailed January 23, 2008 in this case. Attorney Fairman explained to the Examiner that the amendments made to the claims incorporated the limitations of original claim 1, which was a non-elected group and from which instant claim 13, elected in response to the Examiner's restriction, originally depended. Thus, no new matter was added to the claim. Attorney Fairman further pointed out that the limitations of claim 1, were necessary to give claim 13 context in response to the examiners grounds for rejection. Examiner Long agreed with Attorney Fairman and requested this supplemental response for the purpose of entering the filed amendments and examining the claims on the merits. The text of the amendment filed November 5, 2007 is therefore recapitulated in its entirety below. No changes or additions have been made to the November 5, 2007 amendment and response. The Examiner's reconsideration is greatly appreciated.

### Response of November 5, 2007

This paper is in response to the Office Action dated August 8, 2007. In the previous action, the Office issued a restriction requirement between the groups identified as: a method for preparing an evolved microorganism, (Group I); method for preparing an evolved protein, (Group II); an evolved gene (Group III); evolved protein (Group IV); and a method of biotransformation, (Group V). In response, applicants elected to prosecute claims 13-14 drawn to a method of preparing an evolved protein. In this response, claims 1-12 and 15-37 have been cancelled. Claim 13 has been amended herein in independent format to recite all the limitations of claims 1 and 11 from which it depended. The subject matter of original claims 11 and 1 are unaltered, thereby affording the full scope of equivalents for the subject matter. Additionally, the original subject matter of claim 13 remains essentially unaltered, also affording the full scope of equivalents for the original subject matter. Further, the preamble now recites "a method of producing an evolved protein" as originally recited in as-filed claim 13. No new matter has been added by way of this amendment.

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# Rejections Under 35 USC § 102(b)

Claims 13-14 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Schnappinger et al. (Arch. Microbiol. 1996; 165:359-369) (hereinafter "Schnappinger"). In the action, the Office states that Schnappinger et al. teach "The Ribosomal protection proteins encoded by the other classes have an amino acid sequence similarity of at least 40% to Tet(M). Regardless of which gene evolved from which, Tet(M) is an evolved protein in the sense of the instant specification. Schnappinger et al. clearly teach culturing microorganisms comprising the evolved protein Tet(M)."

This rejection is traversed for at least the following reasons.

Claim 13 has been amended herein to recite, in independent format, all the limitations of claim 1 from which it ultimately depended as originally filed. No new matter is added by way of this amendment. As originally filed, Claim 13, recited "A method for the preparation of an evolved protein, wherein the evolved microorganism according to Claim 11 is cultivated in a culture medium appropriate for the production of the evolved protein." As amended herein Claim 13 recites "A method claim for producing an evolved protein" and incorporates the limitations of claims 11 and 1. Claim 13 contains three parts requiring in turn: a) preparing a modified microorganism; b) culturing the modified microorganism on a defined medium to result in an evolved microorganism; and c) selecting the evolved microorganism, wherein the evolved microorganism produces an evolved protein. Specific support for this amendment is found throughout the specification. See, for example, the as filed specification beginning at page 7 and the Examples beginning at page 45 discussing the evolution of the microorganism via the induction of compensatory metabolic pathways.

In contrast, Schnappinger describes naturally occurring ribosomal protection mechanisms including six classes of determinants, Tet M, O-Q, S, OtrA. As noted by the Examiner, Schnappinger et al. clearly teach culturing microorganisms comprising the evolved protein Tet(M). However, claim 13 is a method claim, positively reciting the steps of: a) preparing a modified microorganism that has an impaired ability to grow; culturing the modified microorganisms in a medium that allows it to grow and evolve compensatory metabolic pathways; and c) selecting the evolved microorganisms.

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Schnappinger does not describe this method. Schnappinger did not prepare a modified microorganism by genetic modification of an initial microorganism. Schnappinger did not culture the modified microorganism and Schnappinger did not select an evolved microorganism. Thus, while Schnappinger may describe culturing microorganisms comprising the evolved protein Tet(M), Schnappinger cannot anticipate the instant invention because Schnappinger does not teach all the elements required by claim 13 and claim 14 dependent therefrom. The rejection now being overcome, withdrawal of the rejection is respectfully requested.

### **Double Patenting**

Claims 13-14 are provisionally rejected on the grounds of nonstatutory obviousnessdouble patenting as being unpatentable over claims 16-17 of copending application No. 10/781,499.

The rejection is traversed at least for the following reasons.

Claims 16-17 of U.S. Application No. 10/781,499 were cancelled in the response filed July 16, 2007. Thus, the rejection is overcome and should be withdrawn.

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## CONCLUSION

In view of the above, Applicant respectfully submits that the present application is in condition for allowance. Reconsideration of the present application and a favorable response are respectfully requested. If the restriction requirement requires additional exploration, the Examiner is invited to contact Applicant's representative at the number provided below.

No fee is believed necessary the three-month anniversary of the Office Action November 3, 2007 falling on a Saturday. However, if payment is needed the Commissioner is hereby authorized to charge our Deposit Account No. 04-1420 and notify us of the same.

Respectfully submitted.

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